

REMARKS

Claims 1,3-4, 6-7, 9-10 and 23-38, of which claims 1, 3, 6, 10 and 25-29 are currently amended and claims 30-38 are new, are pending and appear in this application for the Examiner's review and consideration. Claims 1, 10 and 29 are amended to correct a grammatical or typographical error. Claims 3, 6 and 25-26 are amended for definiteness, and amended claim 3 now clarifies what was previously meant by the phrase "of dairy origin." Claims 27-28 are also amended to correct a typographical error such that the claims depend from the correct base claim. New claims 30-38 have been added to cover preferred embodiments of the invention, as supported by the specification and the original claims. The specification is amended, as the Examiner has suggested, at page 5 to clarify that the numbers referenced are GenBank accession numbers, and at page 14 to recite the Gmür article. As no new matter has been introduced, the entry of the claim and specification amendments at this time is respectfully requested.

Applicants also note that a certified copy of the original foreign application, European Application No. 98202707.0, was submitted on June 17, 2004 to perfect the claim of foreign priority.

The Examiner maintains the objection to the references to the genes "X17390," "X14490," and "X53657" in the specification. In response, the second full paragraph on page 5 of the specification has been amended as the Examiner has suggested, to clarify that the numbers refer to GenBank accession numbers. This amendment is fully supported by the specification, for example on page 8, wherein the references are expressly stated to be GenBank accession numbers. Accordingly, this objection should be withdrawn.

The Examiner also maintains the objection with respect to the term "FUM medium," but acknowledges that the term is clearly defined in R. Gmür and B. Guggenheim, "Antigenic Heterogeneity of *Bacteroides intermedius* as Recognized by Monoclonal Antibodies," Infect. Immun. 42, 459-470 (1983). Accordingly, the specification is amended as the Examiner suggests, and now cites the Gmür article on page 14, second full paragraph, of the specification. Thus, all the objections to the specification should be withdrawn.

With respect to the objection of claim 10, the word "herein" is replaced with "wherein" to correct the typographical error.

Claims 6 and 25-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons stated on pages 4-5 of the Office Action. In response, claim 6 is

amended to recite the temperature range of 30°C to 42°C. This temperature range is provided in the specification (see, for example, Example 3). Similarly, the term "about" is deleted from claims 25-26. Accordingly, this claim rejection should be withdrawn.

The Examiner also maintains the rejection of claim 3 under 35 U.S.C. § 112, second paragraph, for indefiniteness of the phrase "of dairy origin." In response, claim 3 is amended to recite lactic bacteria that are originally derived from a dairy. The amended claim clearly shows that the claim is directed to any lactic bacterium that is originally from a dairy, regardless of whether and how many times the bacterium is genetically modified.

Therefore, Applicants respectfully request that all the rejections under § 112, second paragraph, be withdrawn.

Claims 1, 3-4, 6-7, 9-10 and 23-28 remain rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth on pages 5-7 of the Office Action. Applicants respectfully traverse.

The Examiner cites *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) as stating the applicability of both *Univ. of California v. Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997) and *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003) to "methods of using products, wherein said products lack adequate written description." *G.D. Searle* is different from the present application, however, in that the patent at issue did not provide even a single example of the product used in the claimed methods. In contrast, the present specification provides specific examples of lactic bacteria, as the Examiner acknowledges.

The lactic bacteria of the present methods are defined by their specific functions, chemical and physical properties and examples in the present claims and specification, rather than by generalized language as in *G.D. Searle*. In *G.D. Searle*, the Federal Circuit concluded that the claimed methods could not be practiced based on the specification of the patent at issue, because the patent did not disclose *any* compound that could be used in the claimed methods. *G.D. Searle*, 358 F.3d at 927. In fact, there was no evidence that such compound was even known. *Id.* The court concluded that the patent did not meet the written description requirement because the specification failed to disclose "just which peptides, polynucleotides, and small organic molecules have the desired characteristic of selectively inhibiting PGHS-2," the characteristic recited in the claims. *Id.* (internal quotations omitted). Considering *In re Edwards*, 568 F.2d 1349 (C.C.P.A. 1978), in which the written description requirement was held satisfied by a specification that described a claimed compound by the process of

making, rather than by its structure, because the patent application, "taken as a whole," was found to reasonably lead persons skilled in the art to the claimed invention, the court drew a distinction in that the patent at issue "contain[ed] no disclosure of any method for making even a single" compound used in the claimed methods. *Id.* at 928.

In contrast to *S.D. Searle*, the present specification provides specific examples of the lactic bacteria that can be used in the present claims, as the Examiner acknowledges. Hence, while the same written description analysis applies to method claims as to product claims, Applicants believe that the present specification adequately identifies the characteristics of the product used in the claimed methods such that it satisfies the written description requirement. In this respect, Applicants respectfully disagree with the Examiner's statement that "no identifying characteristics of the claimed lactic acid bacteria (i.e., structure/function) are disclosed so as to describe the breadth in Claim 1" (Office Action, p. 7). The identifying characteristics of the present lactic bacteria -- for example, that they are not part of the resident microflora of the human mouth, their low acidifying property of providing a pH in the oral cavity of 5.5 to 7, and their capability of adhering directly to the pellicle of the teeth - - are disclosed both in claim 1 and in the specification. These characteristics clearly distinguish the lactic bacteria that can be used in the present methods from any other lactic bacteria by both their function and their physical and chemical properties. Thus, unlike "a hoped-for function for an as-yet-to-be-discovered compound, and a research plan for trying to find it" in *S.D. Searle* (358 F.3d at 926-27), the present lactic bacteria are known to exist and described by their specific function and physical/chemical properties.

Consideration of the *Amgen* and *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316 (Fed. Cir. 2002) further supports the present application's satisfaction of the written description requirement. As stated in the previous response of December 9, 2003, Applicants, as in *Amgen*, are not attempting to claim some "undescribed, previously unknown DNA sequence." Because the term "lactic bacteria" used in the present claims readily convey distinguishing information concerning their identity, as the terms "vertebrate" and "mammalian" conveyed a distinguishing description of the cells in *Amgen*, Applicants submit that the present application provides an adequate written description under *Amgen*, and respectfully disagree with the Examiner's statement comparing *Amgen* with the present case (p. 6, Office Action). The *Amgen* court stated that both *Eli Lilly* and *Enzo Biochem* were inapposite to the case because "the claim terms at issue [] [were] not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend." Such is

also the case with the present application, since lactic bacteria are not new or unknown biological materials but their identity is clearly conveyed by the term "lactic bacteria." This conclusion is strengthened by Dr. Rudolf Gmür's declaration, previously submitted on December 9, 2003. As supported by Dr. Gmür's declaration, the present disclosure, taken as a whole with the nature of the term "lactic bacteria" (which does not relate to any new or unknown biological materials), provides a sufficient description by teaching the claimed method, exemplary compositions, five deposited lactic acid bacterial strains, and the methods of making or isolating additional lactic acid bacterial strains that could be used in the claimed methods.

Further, as the Federal Circuit stated in *Enzo Biochem*, "[i]t is not correct . . . that all functional descriptions of genetic material fail to meet the written description requirement," because "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, function characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" 296 F.3d at 1324. In addition to holding that a reference in the specification to a deposit in a public depository constitutes an adequate description under § 112, the court suggested that broader genus claims may also satisfy the written description requirement based on a deposit "[i]f those sequences are representative of the scope of the genus claims, i.e., if they indicate that the patentee has invented species sufficient to constitute the genera." *Id.* at 1327. Therefore, given that the present specification provides the physical and chemical properties of the lactic bacteria used in the claimed methods, as well as specific examples of such lactic bacteria, the present genus claims also satisfy the written description requirement, especially since the lactic bacteria are not "new or unknown biological material" but readily convey distinguishing information concerning their identity as explained above.

Accordingly, Applicants submit that the present application provides an adequate written description to meet the requirement of § 112, and respectfully request that the rejection for lack of written description be withdrawn.

Finally, regarding the new claims 30-38, these claims depend from allowed claim 29, and are therefore allowable based on their dependency on claim 29. The support for these claims are found in the original claims and specification, for example, in claims 7, 9-10 and 23-28.

In view of the above amendments and arguments, it is believed that the application is now in condition for allowance, early notification of such would be appreciated. Should the Examiner not agree, a telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the claims.

Respectfully submitted,

Date: 10/7/04



Allan A. Fanucci

(Reg. No. 30,256)

WINSTON & STRAWN LLP

Customer Number 28765

(212) 294-3311